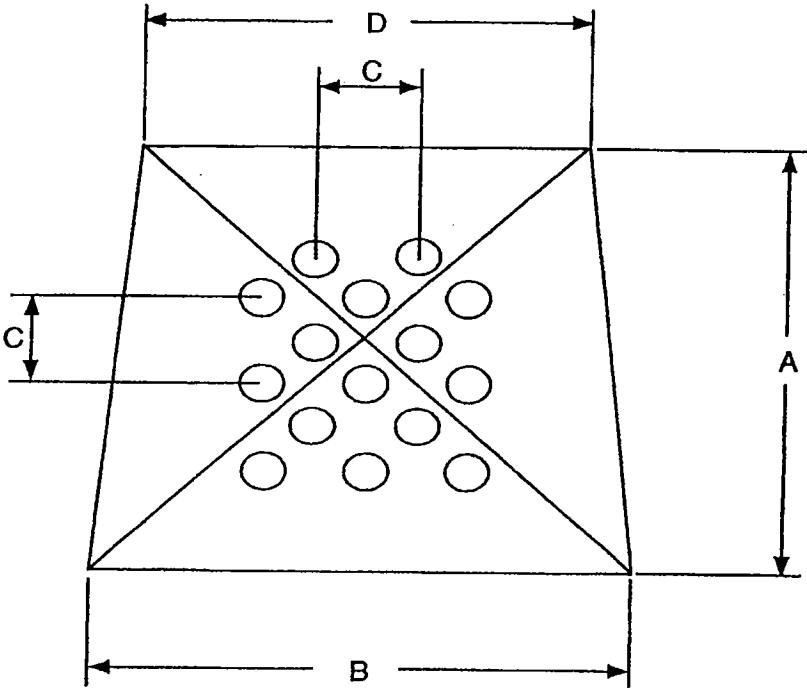


PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/00		A1	(11) International Publication Number: WO 99/16381
			(43) International Publication Date: 8 April 1999 (08.04.99)
(21) International Application Number: PCT/US98/20439			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 30 September 1998 (30.09.98)			
(30) Priority Data: 60/060,730 1 October 1997 (01.10.97) US			
(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SCIMED Place, Maple Grove, MN 55311-1566 (US).			
(72) Inventors: TRIPP, Hugh, A.; 334 Franklin Street, Mansfield, MA 02084 (US); RACKLEY, Raymond; 3199 Falmouth Road, Shaker Heights, OH 44122 (US).			
(74) Agent: TOSTI, Robert, J.; Testa, Hurwitz & Thibault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).			Published With international search report.
(54) Title: PELVIC FLOOR RECONSTRUCTION			
(57) Abstract			
<p>Herniation, including cystocele, rectocele and enterocystocele may be treated with prefabricated repair patches. The repair patches include a natural or synthetic biocompatible material having a shape adapted to support herniated tissue. The patch also contains a plurality of apertures positioned in the central plane of the patch which may permit ingrowth and may also be an attachment site for pexing sutures. The patch may be covered with coating to decrease the possibility of infection, and/or increase biocompatibility. The coating may also include one or more drugs, for example, an antibiotic, an immunosuppressant, and/or an anticoagulant.</p>			
			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

PELVIC FLOOR RECONSTRUCTION

Cross-Reference to Related Application

This incorporates by reference and claims priority to and the benefit of U.S. provisional patent application serial number 60/060,730, which was filed on October 1, 1997.

5

Technical Field

The present invention relates to patches for use in supporting tissues, organs, parts of organs, or other such anatomical structures. The patches may be used in a variety of pelvic floor reconstruction or stabilization procedures, including treatment of cystoceles, rectoceles, enteroceles, or enterocystoceles. More particularly, the present invention relates to prefabricated patches, methods of making the patches, and kits including the patches.

10

Background Information

Damage to the pelvic floor is a serious medical condition which may occur during delivery or due to injury to the vesicovaginal fascia. Such an injury can result in a herniation of the bladder called a cystocele. Other similar conditions are known as rectoceles, enteroceles and enterocystoceles. A rectocele is a herniation of the rectum. An enterocele is formed when the intestine protrudes through a defect in the rectovaginal or vesicovaginal pouch and an enterocystocele is a double hernia in which both the bladder and the intestine protrude. These herniations are serious medical problems that can severely and negatively impact a patient both physiologically and psychologically.

15

20

Treatment of these conditions requires repositioning of the protruding organs or portions thereof. Existing tissue is often compromised facilitating the need to use a synthetic patch. Current medical procedures for repositioning the protruding organs or portions thereof may be time consuming or invasive. Hence, there is a need for reducing the amount of time which these procedures require and the invasiveness of the procedures.

Summary of the Invention

The present invention relates to prefabricated repair patches, methods of making the patches, kits comprising the patches, and methods of using the patches to treat pelvic floor weakening and herniation, including cystoceles, rectoceles, and enteroceles.

5 One aspect of the invention features a prefabricated patch used in pelvic floor reconstruction procedures, including treatment of cystoceles, rectoceles, enteroceles and enterocystoceles. The patch is made of a natural or synthetic biocompatible material suitable for implantation into the body and has a plurality of apertures formed in a central portion of the patch.

10 Embodiments of this aspect of the invention can include the following features. For example, the natural or synthetic biocompatible material may be made of a material which facilitates tissue ingrowth, and it can have a plurality of interstices in which tissue ingrowth may occur. Also, the natural or synthetic biocompatible material may be adapted to be cleanly trimmed with scissors without generating sharp edges or spines. The synthetic biocompatible
15 material can be absorbable, and it can be a woven or knitted material such as Hemashield® (available from Meadox Medical, 112 Bauer Drive, Oakland, NJ 07436). In yet another embodiment of the patch, the natural or synthetic biocompatible material is coated. In some embodiments, the coating on the biocompatible material is absorbed after implantation to facilitate tissue ingrowth into the natural or synthetic biocompatible material. In another
20 embodiment of the patch, the natural or synthetic biocompatible material is impregnated with an antibiotic. In one embodiment, the patch is impregnated with bacitracin. In another embodiment the patch is impregnated with polymyxin. In another embodiment the patch is impregnated with neomycin. In some embodiments, the patch is capable of releasing a drug, and the drug can be released over time.

25 The plurality of apertures formed in the central portion of the patch provide enhanced vascularity and are adapted to permit rapid tissue ingrowth after the patch is installed. The apertures may also be used for pexing sutures. The apertures may be substantially circular. Preferably, the apertures are positioned on the patch at locations which reduce the likelihood of crumpling. For example, the apertures may be positioned at locations which lie outside of the
30 force lines created when the patch is attached to a supporting anatomical structure or tissue. The

apertures may be positioned at locations adapted to equalize the distribution of force on the patch when the patch is attached to a supporting anatomical structure or tissue. In one embodiment the apertures are also adapted for suture attachment or for allowing a suture to pass therethrough. In some embodiments, the material around the periphery of the apertures is reinforced. In other
5 embodiments, the apertures are strengthened with a reinforcing device.

In some embodiments, the corners of the patch are adapted to receive a suture, thus serving as suture attachment sites. In other embodiments, the corners of the patch are adapted to receive more than one suture. In some embodiments, the sutures may be pre-attached to the patch.

10 In another aspect, the invention relates to a kit for performing a pelvic floor reconstruction or stabilization. The kit comprises a sterile natural or synthetic biocompatible material having a shape adapted for use in the procedures discussed above. The natural or synthetic biocompatible material has a plurality of apertures formed therein.

15 In one embodiment of the kit, the patch is packaged and both the patch and packaging are sterile. In another embodiment of the kit, the patch is a filamentous material coated with a coating to decrease the possibility of infection and/or increase biocompatibility. The coating can also include collagen or a polymeric material. In some embodiments, the coating may also include one or more drugs, for example and antibiotic, an immunosuppressant, and/or an anticoagulant. The packaging may be ultra-violet proof to protect the coating and/or drug.

20 Yet another aspect of the invention involves a method of making a patch for use in pelvic floor reconstruction procedures, such as those for treating cystoceles, rectoceles, enteroceles or cystoenteroceles. A natural or synthetic biocompatible material is cut into a shape adapted for pelvic floor stabilization and apertures are formed in the natural or synthetic biocompatible material. The material is typically sterilized, and a coating and/or drug can be applied to the
25 material. The material can then be packaged.

In still another aspect, the invention features a method of stabilizing the pelvic floor. A patch is provided and it comprises a natural or synthetic biocompatible material having a shape adapted for pelvic floor reconstruction and a plurality of apertures formed in a central portion of the patch. One side of the patch is placed in contact with the tissue to be supported. The patch is

secured to a supporting structure such as tissue, fascia, ligament, bone, muscle or other such anatomical structures having sufficient strength to allow the patch to be secured thereto without tearing the supporting structure. The supporting structure is located such that when the patch is secured thereto the herniated tissue is re-positioned in a location which alleviates the hernia. The force applied is sufficient to reposition the tissue in normal anatomical position. One embodiment of this method, the patch is secured by at least one suture which is connected to a bone anchor which is attached to bone. In another embodiment, at least one suture can be attached to anatomical structures other than bone such as the arcus tendinous fascia pelvis, the ileal pectineal, or the pubococcygeous muscle complex.

In one embodiment, the method is a treatment for a cystocele and the tissue to be supported is the bladder or a portion thereof. The patch is placed in contact with the tissue beneath the bladder or portion thereof. The patch is connected to the supporting structure such that a biasing force is applied to the bladder or portion thereof to reposition the bladder or portion thereof such that the cystocele is alleviated. In further embodiments, the supporting structure may be the pubic bone, a ligament, or muscle tissue. The patch may be connected to the supporting structure through a suture or other fastener. In one embodiment, the suture or other fastener is secured to the supporting structure with a securing device such as a bone anchor. In one embodiment of the method, the tissue to be supported further comprises the bladderneck and at least a portion of the patch contacts the bladderneck to provide a biasing force to the bladderneck which repositions the bladderneck. The patch can be trapezoidal in shape and the narrower end of the trapezoid contacts the bladderneck while the wider end of the trapezoid contacts the bladder. In another embodiment of the method, the anchor is positioned in a pubic bone. In yet another embodiment of the method, at least one suture may be attached to the patch at each of the corners. In one embodiment, the method further comprises introducing the patch percutaneously. In another embodiment of the method, the patch is introduced without invasive surgery.

In a further embodiment, the method is a method of treating a rectocele and the tissue to be supported comprises the rectum or a portion thereof. In such procedures, the patch is placed in contact with the rectum or a portion thereof or the tissue adjacent to the rectum or a portion thereof to reposition the rectum or a portion thereof.

In a further embodiment, the method is a method of treating an enterocele and the tissue to be repositioned comprises the intestine or a portion thereof. In such procedures, the patch is placed in contact with the intestine or a portion thereof or the tissue adjacent to the intestine or a portion thereof to reposition the intestine or a portion thereof.

5 In a further embodiment, the method is a method of treating an enterocystocele, and the tissue to be supported comprises the bladder and the intestine or portions thereof. In such procedures, the patch is placed in contact with the bladder and intestine or portions thereof or the tissue adjacent to the bladder and intestine or a portions thereof to reposition the bladder and intestine or a portions thereof.

10 The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being
15 placed upon illustrating the principles of the invention.

Figure 1 is a plan view of a preferred embodiment of the patch of the present invention.

Figure 2 is a plan view of a preferred embodiment of the patch of the present invention showing preferred dimensions.

Figure 3 is a schematic cross-sectional view taken through the urethra and upper vaginal
20 wall illustrating an incision in the upper vaginal wall.

Figure 4 is a schematic cross-sectional view taken through the urethra and upper vaginal wall illustrating a bilaterally extending pocket created by blunt dissection.

Figure 5 is a sagittal section of a female pelvis illustrating the location of the patch relative to the bladderneck and the bladder in a procedure in which both the bladderneck and the
25 bladder are repositioned.

Figure 6 is a cross section of a female pelvis illustrating the location of the patch relative to the bladderneck and the bladder in a procedure in which both the bladderneck and the bladder are repositioned.

Description

5 The present invention relates to prefabricated patches for use in pelvic floor reconstruction. More particularly, the patches are useful in pelvic floor reconstruction procedures, such as procedures for treating cystoceles, rectoceles, enteroceles, and cystoenteroceles.

10 The present patches are designed to be implanted in a patient in whom a hernia has resulted in an organ or portion of an organ protruding from its normal position. For example, the patient may have a cystocele whereby the hernia causes the bladder to protrude from its normal position. Alternatively, the patient may have a rectocele whereby the hernia causes the rectum to protrude from its normal position. The patient may also suffer from an enterocele in which the hernia causes the intestine to protrude from its normal position. In addition, the patient may have
15 a cystoenterocele in which the hernia causes both the bladder and the intestine to protrude from their normal positions.

20 In each of the above conditions, the protruding organ or portion thereof may be restored to its normal position using the present devices and methods. In such procedures, one side of the patch is placed in contact with the organ or portion thereof which is to be repositioned or the tissue adjacent to the organ or portion thereof which is to be repositioned. The patch is secured to a support structure through a fastener such as a suture. The support structure may be any structure having sufficient strength to allow the support to be secured thereto without tearing the support structure. For example, the support structure may be bone, fascia, ligament or muscle. The support structure is positioned such that when the patch is secured thereto, the patch will
25 apply a biasing force to the tissue to be repositioned such that the tissue to be repositioned is restored to its normal position.

 The patches of the present invention comprise a natural or synthetic biocompatible material having a plurality of apertures therein. The biocompatible material may be any of a variety of materials. In some embodiments the patch may be made of a material which facilitates

tissue ingrowth. For example, the patch may be made of a material having a plurality of interstices, openings or pores therein which permit tissue ingrowth.

The patch may be fabricated from any of a variety of biocompatible materials. Such materials may be naturally occurring or synthetic, non-filamentous or filamentous, elastic or inelastic, and may be porous, microporous, perforated, or impermeable. The properties of the patch may be selected as appropriate based on the surgical procedure used to implant the patch and the application for which the patch is used.

Synthetic polymeric materials including, polyester such as Hemashield[®], polytetrafluoroethylene (PTFE) such as GoreTex[®], polyethylene terephthalate (PET), fluorinated ethylene propylene resin (FEP), polyurethane, or nylon can also be used to form the patches. The synthetic polymeric material can be woven, knitted, or nonknitted. In one embodiment, filaments made from synthetic materials may be braided together to form strands or threads which can be woven, braided, or knitted together to form strips of fabric. Preferably, the synthetic filamentous material is polyester. In one embodiment of the patch, the biocompatible material may be adapted to be cleanly trimmed with scissors without generating sharp edges or spines.

In a preferred embodiment the patch may be made of knitted collagen coated polyester such as Hemashield[®] (available from Meadox Medical, 112 Bauer Drive, Oakland, NJ 07436).

The patch can be made from natural materials using autologous, allogenic, or xenogenic material. The natural material can be fibrous tissue, fascia including the fascia lata and rectus fascia, dura, pericardium, striated muscle or part of the vaginal wall. Tissue from xenogenic or allogenic sources may be freeze dried to reduce the immune response to the implanted patch. Patches made from natural material include a plurality of apertures formed in the center portion and can be a shape adapted to support herniated tissue and/or the bladderneck.

Additionally, the patch material may be impregnated with antibiotics or other agents which can be delivered from the surface of the patch as well as through the pores, micropores or perforations. Impregnation with antibiotics or other agents may be facilitated by coating the patch with collagen.

A coating may also be applied to the patch. The coating may be applied to the surface of the material or may be impregnated within the material. The coating may be used to deliver a number of compounds, such as antibiotics, anticoagulant agents, e.g., heparin, immunosuppressant agents and/or other drugs. In some embodiments, the drug may be released over time. The coating also blocks the interstices of the underlying patch material, thereby decreasing the risk of infection by sequestering the interstices of the patch from contact with microorganisms encountered during implantation of the patch. Preferably, the coating is absorbed after implantation to facilitate tissue ingrowth into the interstices, pores, micropores and/or perforations of the patch material.

Suitable coatings include polyglycolic acid, polylactic acid, blends of polyglycolic acid and polylactic acid, gelatin, polyvinyl alcohol, and polyvinyl pyrrolidone. A preferred coating is a smooth layer of collagen, such as that provided on the Hemashield® available from Meadox. (Meadox Medical, 112 Bauer Drive, Oakland, NJ 07436 or Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760.) The smooth collagen coating protects the interstices of the underlying patch material from bacterial contact during implantation, thereby decreasing the risk of infection as previously discussed. The collagen coating can also enhance tissue compatibility. Additionally, the collagen coating can facilitate the uptake of antibiotics to reduce the risk of infection. After placement in the body, the collagen is gradually absorbed, facilitating tissue ingrowth into the underlying filamentous material.

The patches of the present invention can also be made of absorbable materials. Such absorbable patches preferably remain structurally intact for at least three months while supporting tissue ingrowth. Thereafter, the patches may be fully absorbed. Preferably, the patches are fully absorbed over a period of months following the three month period in which the patch is intact. Preferably, the absorbable patch is made of polylactic acid or polylactic acid/polyglycolic acid copolymers.

The patch may have a variety of shapes adapted for use in pelvic floor reconstruction procedures. For example, the patch may be trapezoidal, square, rectangular, oblong, ovoid, or may be an elongated incurvate shape. Those skilled in the art will appreciate that the patch may have a variety of other shapes depending on the procedure in which it is being used and the materials of which it is made.

The patch has a plurality of apertures therein which provide enhanced vascularity and are adapted to permit rapid tissue ingrowth after the patch is installed. The apertures may also be used for pexing sutures. Preferably, the apertures are positioned on the patch at locations which reduce the likelihood of crumpling. For example, the apertures may be positioned at locations
5 which lie outside of the force lines created when patch is attached to a supporting anatomical structure or tissue. The apertures may be positioned at locations adapted to equalize the distribution of force on the patch when the patch is attached to a supporting anatomical structure or tissue. In one embodiment the apertures are also adapted for suture attachment or for allowing a suture to pass therethrough. In some embodiments, the material around the periphery of the
10 apertures is reinforced as described in U.S. Patent Application entitled, "Stabilization Sling for Use in Minimally Invasive Pelvic Surgery," Serial No. 09/023,398, filed February 13, 1997, which is hereby incorporated by reference. In embodiments using synthetic material, the material around the periphery of the aperture can be reinforced by heat sealing or ultrasonic sealing the material. The apertures can also be strengthened with a reinforcing device as
15 described in U.S. Patent Application entitled, "Stabilization Sling for Use in Minimally Invasive Pelvic Surgery," Serial No. 09/023,398, filed February 13, 1997, which is hereby incorporated by reference. For example, reinforcing devices can be inserted into the material. The reinforcing device can define the periphery of the aperture and strengthen the patch in the area of the apertures. In a preferred embodiment, the one piece reinforcing device can be made from
20 biocompatible plastics or metals, such as stainless steel or titanium. Alternatively, a multiple piece interlocking reinforcement device can be inserted into the material.

In some embodiments, the corners of the patch are adapted to receive a suture, thus serving as suture attachment sites. In other embodiments, the corners of the patch are adapted to receive more than one suture. In some embodiments, the sutures may be pre-attached to the
25 patch.

Referring to Figure 1, there is disclosed a plan view of a preferred embodiment of the patch 10 of the present invention. The patch of Figure 1 has been cut into a generally elongate trapezoid shape adapted for pelvic floor reconstruction, with a central plane extending between a more narrow first end 16 and a wider second end 18. Introduced into the natural or synthetic
30 biocompatible material are a plurality of tissue ingrowth apertures 12. Tissue ingrowth apertures are prefabricated in the central plane of the patch 10. The cross lines 14 represent force lines

along which tension is transmitted when the patch is attached to the supporting structure at the corners. In a preferred embodiment, the apertures are positioned so that they lie outside of the force lines.

The dimensions of a preferred embodiment are shown in Figure 2. The approximate
5 dimensions, in inches, are as follows: A=1.97; B=2.17; C=0.4; and D=1.78. Preferably, the diameter of the apertures is 0.17 inches. However, those skilled in the art will appreciate that the dimensions of the patch may vary depending on the procedures in which it is used and anatomical variations.

The present patches may be cut into the desired shape prior to providing them to the
10 physicians. This eliminates the need for the physician to cut the patch material into the desired shape during the surgical procedure, thereby reducing the time of the procedure as well as the complexity of the procedure. In addition, providing the patches in precut form may reduce the amount of tissue dissection required for the implantation procedure because the chance that the physician will cut the patch into a size or shape which does not minimize the amount of tissue
15 dissection is eliminated. The patches of the present invention may be individually packaged and/or sterilized prior to purchase. The packaging may protect the patch during storage. For example, in embodiments in which the patch material comprises a collagen coated filamentous material, the packaging may protect the patch from damage by ultraviolet light. The patch may be soaked in an antibiotic solution, such as a solution of neomycin, bacitracin, or polymyxin, to
20 prevent microorganisms from collecting on and colonizing the surface of the patch during manipulation, thereby reducing the risk of infection following implantation of the patch. The patch may also be sterilized by ethylene oxide or irradiation. Uptake and delivery of the antibiotic may be enhanced by using a coated patch as described above. In additional embodiments, the patch may be provided to the physician with the sutures pre-attached.

25 Use of the patch to treat a condition in which an organ or portion thereof protrudes from its normal position will now be described using treatment of a cystocele as an example. If desired, the bladderneck may be stabilized in addition to repositioning the bladder.

A minimally invasive percutaneous method of patch delivery and stabilization to treat an incontinent patient will now be described with reference to Figures 3-6. Preoperatively, the
30 patient receives broad spectrum antibiotics, such as gentamicin and ampicillin. The patient is

-11-

placed in the dorsal lithotomy position and regional or general anesthesia is administered. Preparation of the patient emphasizes isolation of the anus with a stapled towel or plastic drape. A Foley catheter is placed.

5 A midline incision 20 is made in the upper vaginal wall 22 beneath the bladderneck, such as at the urethro-vesical junction as illustrated in Figure 3. The surgeon then inserts an instrument such as surgical scissors through the incision in the upper vaginal wall and bluntly dissects the tissue 26 on both sides of the urethra to create a bilaterally extending pocket which is illustrated in Figure 4.

10 The bilaterally extending pocket can also be created and the patch can be inserted using a variety of other minimally invasive instruments/methods including the transvaginal, hiatal and percutaneous approaches disclosed in the U.S. Patent Application entitled "Transvaginal Anchor Implantation Device," Serial No. 08/744,439 filed November 8, 1996, the U.S. Patent Application entitled "Percutaneous and Hiatal Devices and Methods for Use in Minimally Invasive Pelvic Surgery" Serial No. 09/023,965 filed February 13, 1997, and the U.S. Patent
15 Application entitled "Method and Apparatus for Minimally Invasive Pelvic Surgery" Serial No. 09/023,533, filed February 13, 1997, which are hereby incorporated herein by reference.

Either before or after creating the pocket 28, a bone anchor 30, such as a screw in anchor, a press in anchor, or a punch in anchor, is introduced into the pubic bone 34 for fixation of suspensory sutures, with or without predrilling a hole in the pubic bone. For instance, the bone
20 anchor is introduced using a bone anchor implantation device of a type such as that illustrated in Figures 15-19 of U.S. Patent No. 5,766,211, entitled "Bone Anchor Implantation Device", filed February 9, 1995, which is hereby incorporated herein by reference. Bone anchor sites are located by placing the bone anchor implantation device on the body over the area of the pubic bone after visualization or digital palpation over the bone. The surgeon then extends the bone
25 probes distally until both probes have made contact with the pubic bone. Preferably, one anchor 30 for each side (two per patient) is implanted into the tubercle portions of the pubic bone. Preferably, the eyelet of the anchor is recessed below the surface of the bone or flush with the surface of the bone. The anchor 30 preferably has a suture 32 slidably secured thereto prior to implantation of the anchor into the pubic bone so that a first suture end and a second suture end
30 extend from the implanted anchor after removal of the anchor driver.

-12-

Two separated approximately one inch transverse incisions are made over the pubic bone as illustrated in the U.S. Patent No. 5,611,515 entitled "Bladderneck Suspension Procedure", which is hereby incorporated herein by reference, and dissection is carried down to the area of the rectus fascia. The first end of the anchored suture is manually placed into a suture channel of
5 a suture passer of a type such as that illustrated in Figures 45 and 45a of the above incorporated U.S. Patent No. 5,611,515 entitled "Bladderneck Suspension Procedure." The probe is moved distally to lock the suture therein.

Beginning on the right side, the suprapubic wound is stretched cephalad to allow the vertical passage of the suture passer through the rectus fascia with the probe tip fully exposed.
10 Distal advancement of the suture passer is accomplished with the tip proximally retracted within the probe guide. The suture passer is acutely angled into the abdomen so that the point rests on the underside of the pubic periosteum.

While maintaining contact with the underside of the pubis, the suture passer with the probe tip retracted is thereafter passed distally toward the introitus. At the completion of this
15 distal passage, the suture passer can be palpated through the introitus to the right of the urethra 24. The distal end tip of the suture passer is withdrawn from the surface of the pubourethral ligament and gently swept along the pubocervical fascia to the area of the bladderneck under the guidance of a finger within the vagina. Palpation through the vagina may be safely performed to assist in localization of the suture passer tip.

20 The probe tip is then distally extended. The suture passer is then passed through the endopelvic fascia and into the pocket 28 between the urethra 24 and the upper vaginal wall 22 at which time the probe tip is retracted. The surgeon then guides the suture passer distally into the vagina through the midline incision 20 in the upper vaginal wall 22. The probe is then retracted maximally to the unlocked position to allow the first end of the suture to be manually removed
25 from the suture channel.

The surgeon selects a patch 10, such as patch of the present invention. The surgeon then attaches the sutures 32 to the patch. This step is unnecessary in embodiments where a suture is pre-attached to the repair patch of the invention. If desired, the suture may also be passed through one or more apertures in the patch.

After securing the sutures to the patch, the first end of the suture is placed into the unlocked suture channel and locked into place. The suture passer and suture locked therein are then pulled up through the suprapubic wound. The first end of the suture is then released from the suture channel by manually retracting the probe.

5 The identical procedure is performed on the left side.

The surgeon places the patch 10 into the pocket 28 through the midline incision 20 in the upper vaginal wall 22. At least a portion of the patch is placed under the cystocele. Where it is desired to stabilize the bladderneck as well as to reposition the bladder, at least a portion of the patch is placed beneath the bladderneck.

10 As will be apparent to one of skill in the art, the patch may be placed beneath the bladderneck in a variety of ways other than via the pocket 28.

After placing the patch in the pocket or opening, the surgeon aligns the patch. The sutures cause the patch to provide a biasing force on the bladder sufficient to support the bladder in a location which alleviates the cystocele. In addition, if a portion of the patch is under the
15 bladderneck, the patch realigns the bladderneck and the urethra to the correct anatomical position. As will be apparent to one of skill in the art, alignment of the patch relative to the bladderneck and the bladder can be accomplished in a variety of ways, such as by direct visualization.

If the patch is trapezoidal in shape and if it is desired to stabilize the bladderneck as well
20 as to reposition the bladder, the narrower end of the trapezoid is preferably positioned beneath the bladderneck and the wider end is preferably positioned beneath the bladder.

After the patch is correctly positioned, the sutures on each side are tied with sufficient tension to reposition the bladder, and, if desired, to support the bladderneck as illustrated in Figure 5. The Foley catheter is removed prior to tying the suspensory sutures.

25 Referring to Figure 6, in one embodiment, the one or more of the sutures 32 can be laterally attached to anatomical support structures other than the pubic bone, for example, the ileal pectineal (termed Cooper's ligament) 36, the arcus tendinous fascia (termed the White Line) 38, or the pubococcygenous muscle complex 40. In Figure 6, the smaller side of the patch 42 is

attached to the pubic bone 34 and the larger side 44 is attached to the arcus tendinous fascia pelvis (termed the White Line).

In order to minimize postoperative urinary blockage caused by excessive tension, suture tension is regulated by tying the first and second ends of the sutures across a suture tensioner of a type such as that illustrated in Figures 46-49 of the above incorporated U.S. Patent No. 5,611,515
5 entitled "Bladderneck Suspension Procedure", filed April 5, 1993. The suture tensioner is thereafter removed and the position of the patch is reconfirmed prior to closing the vaginal and suprapubic wounds.

The wounds are irrigated with an antibiotic solution, such as a bacitracin solution. The
10 wound edges and the rectus fascia at the suture entry points are infiltrated with bupivacaine. A Foley catheter is introduced. Alternatively, a suprapubic tube can be placed, especially in those patients having dexterity problems or an aversion to learning intermittent catheterization.

Following surgery, the patient is given either ciprofloxacin or ofloxacin for ten days. For those patients having a Foley catheter, the catheter is removed approximately one week
15 following surgery. The patient performs intermittent catheterization as necessary until the postvoid residuals are less than 75 cc on two consecutive catheterizations. In patients having a suprapubic tube, the suprapubic tube is removed when the postvoid residuals are less than 75 cc following two consecutive urinations.

While the foregoing procedure was described using two bone anchors per patient, one of
20 ordinary skill in the art will recognize that the procedure could also be accomplished using either one anchor per patient, greater than two anchors per patient, other types of surgical fasteners or no surgical fasteners at all.

The patch invention disclosed here is designed to be attachable to any suitable support structure. Examples of such structures include but are not limited to the ligaments, fascia and
25 appropriate muscle structures proximate to the site of attachment. For example, the sutures may be attached to the Cooper's ligament or the rectus fascia without using bone anchors.

All references cited herein are incorporated herein by reference in their entirety.

Although this invention has been described in terms of certain preferred embodiments, other embodiments, which will be apparent to those of ordinary skill in the art in view of the disclosure herein are also within the scope of this invention.

What is claimed is:

Claims

1 1. A surgical patch comprising a piece of biocompatible material having a plurality of
2 apertures formed in a central portion of the piece of the material.

1 2. The surgical patch of claim 1 wherein at least one of the plurality of apertures
2 comprises a substantially circular hole in the piece of material.

1 3. The surgical patch of claim of 1 wherein the piece of material is capable of being
2 trimmed with scissors.

1 4. The surgical patch of claim 1 wherein the biocompatible material includes a plurality
2 of interstices.

1 5. The surgical patch of claim 1 wherein the apertures permit tissue ingrowth after the
2 patch is installed in a body.

1 6. The surgical patch of claim 1 wherein the apertures are reinforced.

1 7. The surgical patch of claim 1 wherein the piece of material includes four sides.

1 8. The surgical patch of claim 7 wherein the sides form a trapezoidal shape.

1 9. The surgical patch of claim 7 wherein the apertures are located in the central portion
2 of the piece of material away from the sides.

1 10. The surgical patch of claim 1 wherein the piece of material comprises a knitted
2 material.

1 11. The surgical patch of claim 10 wherein the knitted material comprises a polymer.

1 12. The surgical patch of claim 1 wherein the patch is capable of releasing a drug.

1 13. The surgical patch of claim 1 wherein the piece of material includes a coating.

1 14. The surgical patch of claim 13 wherein the coating includes heparin.

1 15. The surgical patch of claim 13 wherein the coating includes an antibiotic.

- 1 16. The surgical patch of claim 13 wherein the coating comprises collagen.
- 1 17. The surgical patch of claim 13 wherein the coating comprises polyglycolic acid.
- 1 18. The surgical patch of claim 13 wherein the coating comprises polyactic acid.
- 1 19. The surgical patch of claim 13 wherein the coating comprises gelatin.
- 1 20. The surgical patch of claim 13 wherein the coating comprises polyvinyl alcohol.
- 1 21. The surgical patch of claim 13 wherein the coating comprises polyvinyl pyrrolidone.
- 1 22. The surgical patch of claim 13 wherein the coating is absorbable by a body.
- 1 23. The surgical patch of claim 1 wherein the piece of material is absorbable by a body.
- 1 24. The surgical patch of claim 7 wherein the piece of material also includes four corners
2 and each corner is adapted to be attached to an anatomical structure by a surgical fastener,
3 thereby forming a first force line extending from one of the corners to a diagonally opposite one
4 of the corners and a second force line extending from a different one of the corners to a
5 diagonally opposite one of the corners, the apertures being located outside of the force lines.
- 1 25. The surgical patch of claim 24 wherein a the surgical fastener is a suture.
- 1 26. The surgical patch of claim 24 including a first end approximately 1.97 inches long
2 and a second end approximately 2.17 inches long.
- 1 27. The surgical patch of claim 24 including third and fourth ends approximately 1.78
2 inches long.
- 1 28. The surgical patch of claim 24 wherein the apertures are approximately 0.17 inches in
2 diameter.
- 1 29. The surgical patch of claim 24 wherein the apertures are spaced approximately 0.4
2 inches apart.
- 1 30. A method of making a surgical patch, comprising:
2 providing a biocompatible material;

3 cutting the material into a shape adapted for treatment of herniation in a body;

4 forming a plurality of apertures in a central portion of the material;

5 sterilizing the material; and

6 applying a coating to the material.

7 31. The method of claim 30 further comprising packaging the material in a sterile, ultra-
8 violet-proof container.

1 32. The method of claim 30 wherein the sterilizing step comprises irradiating the
2 material.

1 33. The method of claim 30 wherein the sterilizing step comprises heating the material.

1 34. The method of claim 30 wherein the sterilizing step comprises exposing the material
2 to ethylene oxide.

1 35. The method of claim 30 wherein the applying step further comprises applying
2 collagen to the material.

1 36. The method of claim 30 further comprising applying a drug to the material.

1 37. The method of claim 36 wherein the applying a drug step comprises applying an
2 antibiotic to the material.

1 38. The method of claim 36 wherein the applying a drug step comprises applying an
2 immunosuppressant to the material.

1 39. A method of treating herniation in a body, comprising:

2 providing a surgical patch comprising a piece of biocompatible material capable of being
3 trimmed and having a plurality of apertures formed in a central portion of the piece of material;
4 and

5 securing the patch to anatomical support in the body with at least one surgical fastener to
6 treat the herniation such that the patch applies a force sufficient to restore the herniated tissue to
7 normal anatomical position.

1 40. The method of claim 39 wherein the patch further comprises a trapezoidal shape and
2 the securing step further comprises contacting the bladder with the wider end; and contacting the
3 bladderneck with the narrower end.

1 41. The method of claim 39, further comprising pexing the patch through at least one
2 aperture.

1 42. The method of claim 39 wherein the anatomical support in the body includes bone.

1 43. The method of claim 39 wherein the anatomical support in the body includes muscle.

1 44. The method of claim 39 wherein the anatomical support in the body includes fascia.

1 45. The method of claim 39 wherein the anatomical support in the body includes
2 ligament.

1 46.. The method of claim 39 wherein the herniation is a cystocele.

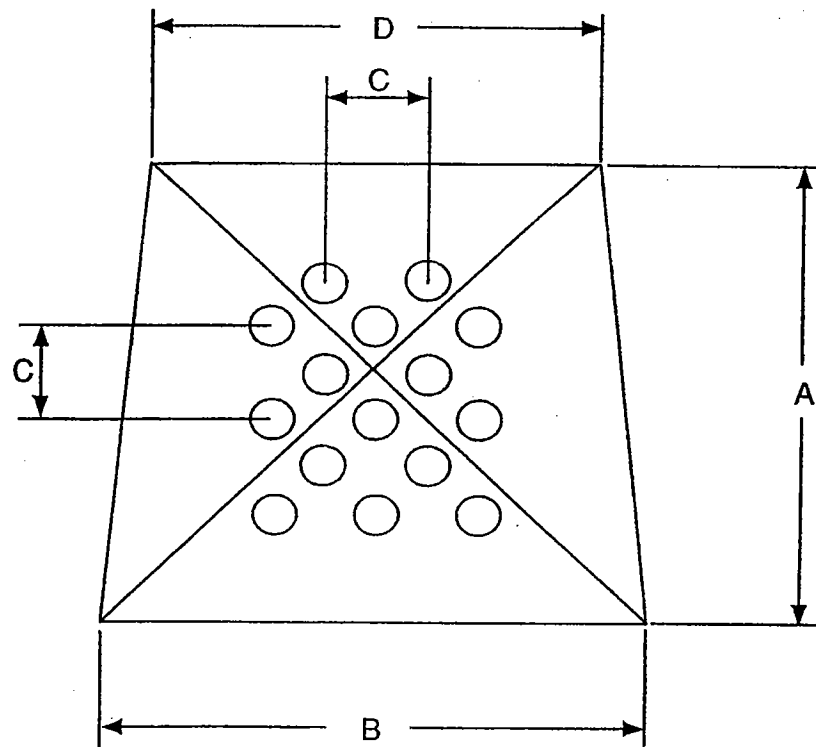
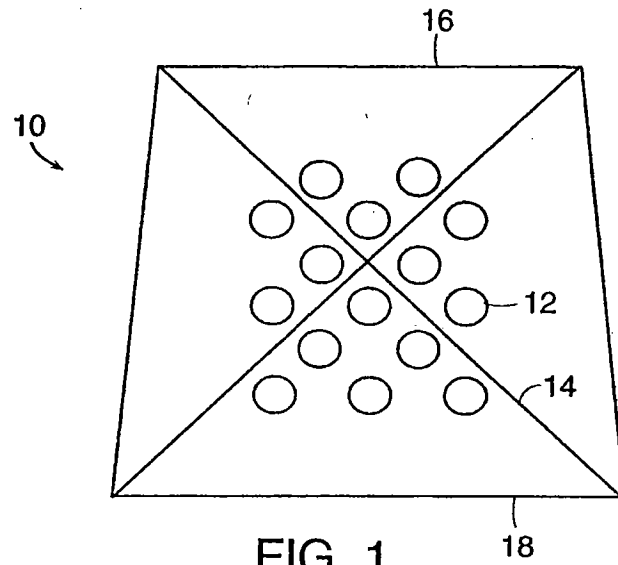
1 47. The method of claim 39 wherein the herniation is a rectocele.

1 48. The method of claim 39 wherein the herniation is a enterocele.

1 49. The method of claim 39 wherein the patch is introduced transvaginally.

2 50. The method of claim 39 wherein the patch is introduced percutaneously.

1/3



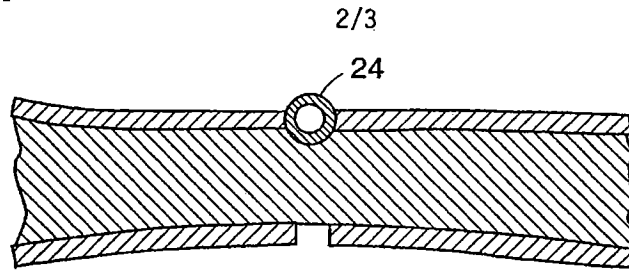


FIG. 3

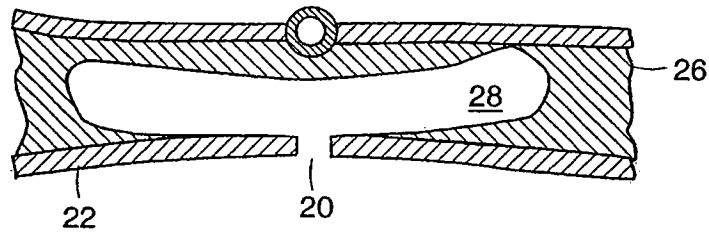


FIG. 4

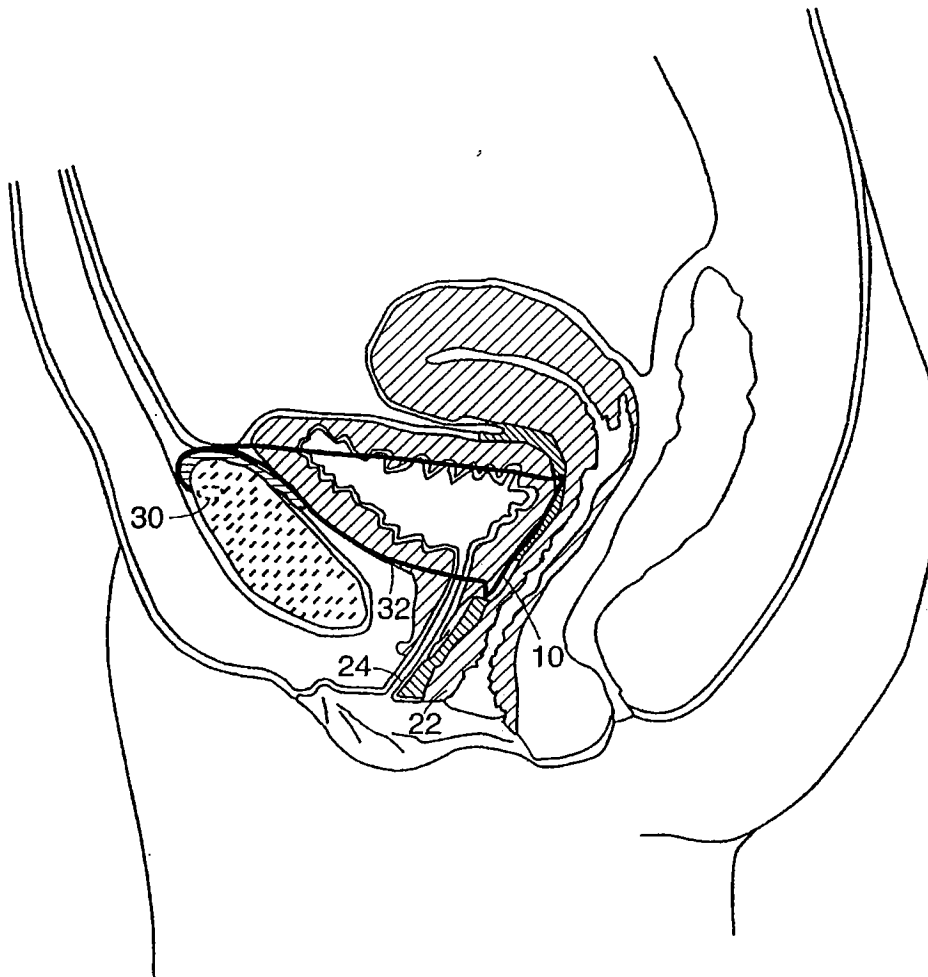


FIG. 5

3/3

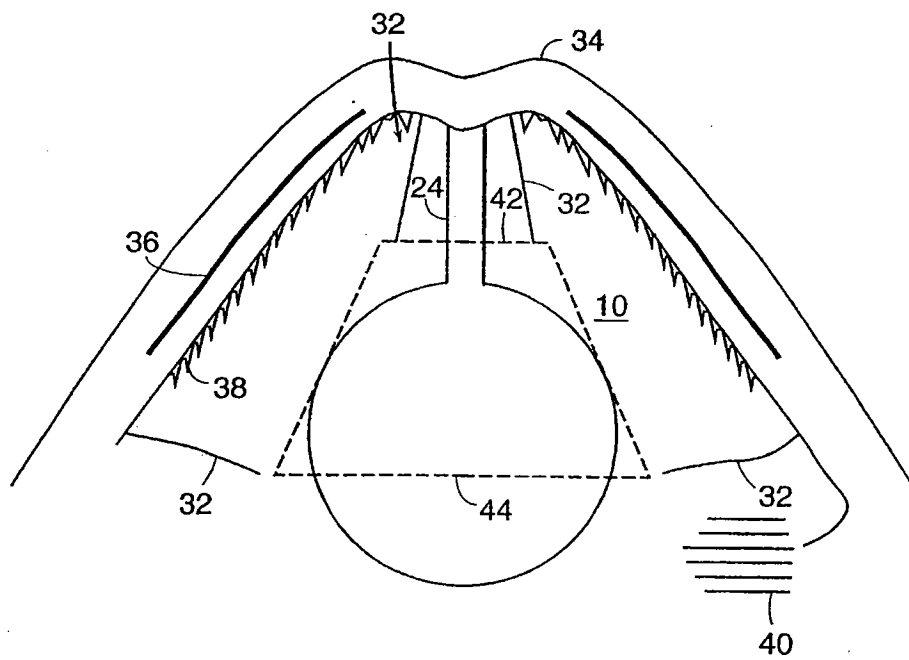


FIG. 6

INTERNATIONAL SEARCH REPORT

international Application No
PCT/US 98/20439

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 94 19029 A (GORE & ASS) 1 September 1994 see page 3, line 1 - line 24; figures	1,2,7, 10,11 3,4,9, 24,25, 28,30
X A	WO 93 10731 A (KENSEY NASH CORP) 10 June 1993 see the whole document	1-3,7, 12,13, 15-19, 22,23 24,25, 30,33, 35-37

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

7 January 1999

Date of mailing of the international search report

15/01/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Neumann, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20439

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 854 316 A (DAVIS EMSLEY A) 8 August 1989 see column 3, line 31 - column 4, line 23; figures	1,2,4,5, 7,10,11
A	---	24,25,30
X	WO 88 01853 A (AUDION MICHEL) 24 March 1988 see page 1, line 21 - line 33; figure 11 see page 5, line 4 - line 17	1,2,5, 12,23
A	-----	13,15, 17,22, 30,34, 36,37

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/20439

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 39-50
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/20439

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9419029 A	01-09-1994	US 5433996 A CA 2155326 A EP 0684844 A JP 8506750 T US 5614284 A	18-07-1995 01-09-1994 06-12-1995 23-07-1996 25-03-1997
WO 9310731 A	10-06-1993	AU 3242693 A	28-06-1993
US 4854316 A	08-08-1989	NONE	
WO 8801853 A	24-03-1988	FR 2604085 A	25-03-1988